



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,318	12/06/2000	Steve Paboojian	015225-005420US	1028

21968 7590 07/24/2002

INHALE THERAPEUTIC SYSTEMS, INC
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

MENDOZA, MICHAEL G

ART UNIT PAPER NUMBER

3761

DATE MAILED: 07/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

.09/731,318

Applicant(s)

PABOOJIAN ET AL.

Examiner

Michael G. Mendoza

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 54 and 60. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: Z, A, B, and d. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: Specification fails to describe reference letters Z, A, B, and d.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 32 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 32 depends on itself.
7. Claim 36 depends on itself.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Melton, Jr. et al. 3,967,761.
10. As to claim 1, Melton, Jr. et al. teaches a receptacle for holding fine powders, the receptacle comprising: a receptacle body that defines an enclosed cavity, wherein the receptacle body has a top end, and wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity (fig. 11 and 12).
11. As to claim 2, Melton, Jr. et al. teaches a receptacle as in claim 1, wherein the receptacle body further comprises at least one curved wall that in combination with the raised central region forms a generally semi-toroidal geometry in the cavity (fig. 11 and 12).
12. As to claim 3, Melton, Jr. et al. teaches a receptacle as in claim 1, wherein a portion of the bottom end is flat in geometry (fig. 15 and 16).

13. As to claim 4, Melton, Jr. et al. teaches a receptacle as in claim 1, wherein the receptacle body further includes a tab extending from the cavity (fig. 6 and 11).

14. Claims 23, 25, 26, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. 5,740,794.

15. As to claim 23, Smith et al. teaches the method for aerosolizing a powdered medicament, the method comprising: providing a receptacle comprising a receptacle body that defines an enclosed cavity, wherein the receptacle body has a top end and a bottom end 342; inserting a bottom end of an extraction tube 370 into the cavity such that the bottom end of the extraction tube is spaced above the bottom end of the receptacle (fig 19); forming vents in the top end of the receptacle about a periphery of the cavity (col. 17, lines 16-37); and flowing a gas stream through at least a portion of the extraction tube to draw air through the vents and then through the cavity to move the powder in the cavity into the extraction tube where the powder is entrained in the gas stream to form an aerosol (col. 13, lines 49-63); and wherein the air drawn by the gas stream flows through a flow area, and further comprising reducing the flow area as the air flows through the receptacle and the extraction tube to accelerate the flow of air through the receptacle (fig. 12 b-c).

16. As to claim 25, Smith et al. teaches a method as in claim 23, further comprising releasing an amount of pressurized gas to produce the gas stream (col. 13, lines 22-26).

17. As to claim 26, Smith et al. teaches a method as in claim 23, wherein the vents form a first flow area, wherein a gap between the extraction tube and the bottom end of

Art Unit: 3761

the receptacle defines a second flow area, and wherein a cross section of the extraction tube defines a third flow area, and wherein the first flow area is greater than the second flow area, and wherein the second flow area is greater than the third flow area (fig. 19).

18. As to claim 35, Smith et al. teaches a powder extraction system, comprising: at least one receptacle that defines an enclosed cavity that holds a powder, wherein the receptacle has a top end and a bottom end 342; a holder to hold the receptacle 340; an extraction tube 370 that is insertable into the cavity; a vent forming 372 device to form vents in the top end of the receptacle (fig. 19), wherein the vents form a first flow area, wherein a gap between the extraction tube and the bottom end of the receptacle defines a second flow area, and wherein a cross section of the extraction tube defines a third flow area (fig. 19), and wherein the holder is configured to move the receptacle relative to the bottom end of the extraction tube such that the first flow area is greater than the second flow area, and wherein the second flow area is greater than the third flow area to accelerate a gas flowing through the receptacle (col. 13, lines 6-9; fig. 19).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Seager 4,548,524.

21. As to claim 5, Smith et al. teaches a receptacle as in claim 1. It should be noted that Smith fails to teach a central hole in the top end and multiple vents, and a cover removably attached to the top end to cover the hole and the vents. However, Seager does teach does teach a central hole 14 in the top end and multiple vents 22 (col. 3, lines 46-48), and a cover 30 removably attached to the top end to cover the hole and the vents. Therefore it would have been obvious to one of ordinary skill in the art to modify the receptacle of Smith to include the central hole, multiple vents, and cover to provide protection and to allow removal of the powder enclosed in the cavity.

22. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Newell et al. 4,778,054.

23. As to claim 24, Smith et al. teaches a method as in claim 23. It should be noted the Smith et al. fails to teach a patient inhaling to produce the gas stream. However Newell et al. does teach a patient inhaling to produce the gas stream (col. 3, lines 53-61). Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Smith et al. to include the step of Newell et al. to eliminate the need to replace a pressurized gas source when it is exhausted.

24. Claims 6, 8-10,12, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Ohki et al. 5,921,236.

25. As to claim 6, Smith et al. teaches a method for aerosolizing a powder, the method comprising: providing a receptacle having a top end, a bottom end, and a cavity containing a powder 342; inserting a bottom end of an extraction tube 370 into the cavity such that the bottom end of the extraction tube is spaced above the bottom

Art Unit: 3761

end of the receptacle (fig. 19); forming at least one vent 202 in the cavity. It should be noted that Smith et al. fails to teach forming a hole in the bottom end of the cavity; and flowing a gas stream through the hole in the bottom end of the receptacle and through at least a portion of the extraction tube to cause air to be drawn through the vent and then through the cavity to move the powder in the cavity into the extraction tube where the powder is entrained in the high pressure gas stream to form an aerosol. However, Ohki et al. does teach forming a hole in the bottom end of the cavity; and flowing a gas stream through the hole in the bottom end of the receptacle and through at least a portion of the extraction tube to cause air to be drawn through the vent and then through the cavity to move the powder in the cavity into the extraction tube where the powder is entrained in the high pressure gas stream to form an aerosol (col. 8, lines 9-16).

Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Smith et al. to include the method step of Ohki et al. to mix high pressure air with the powder and to facilitate mixing and delivery of the powder.

26. As to claim 8, Smith/Ohki teaches the method as in claim 6, further comprising capturing the aerosolized powder in a capture chamber 304.

27. As to claim 9, Smith/Ohki teaches the method as in claim 6, further comprising forming multiple vents in the top end of the receptacle about a periphery of the cavity such that air is drawn through substantially all of the cavity to remove the powder (col. 17, lines 16-18).

28. As to claim 10, Smith/Ohki teaches the method as in claim 6. Smith/Ohki teaches a method for forming a vortex wherein the means for forming a vortex

comprises air flow channels 120 formed in a spiral pattern. It should be noted that Smith/Ohki fails to specifically teach the particulars of the vortex forming means as set forth by the above claim. However, the particulars of the vortex forming means are mechanical expedients of each other and are old and known in the air flow art.

29. As to claim 12, Smith/Ohki teaches the method as in claim 6, further comprising releasing an amount of pressurized gas to produce the gas stream (col. 13, lines 22-26).

30. As to claim 28, Smith/Ohki teaches an apparatus for aerosolizing a powdered medicament, the apparatus comprising: a housing 302 having a holder 340 that is adapted to receive a receptacle 342 having a cavity that holds a powder; a piercing mechanism 27 that is adapted to pierce a hole in a bottom end of the receptacle; a vent forming mechanism 372 for forming multiple vents in a top end of the receptacle (fig. 19); and an extraction tube 370 that is adapted to be placed into the cavity so as to be spaced above the bottom end of the receptacle and to be aligned with the hole in the bottom end.

31. Claims 11 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Ohki et al. in further view of Newell et al.

32. As to claim 11, Smith/Ohki teaches the method as in claim 6. It should be noted the Smith/Ohki fails to teach a patient inhaling to produce the gas stream. However Newell et al. does teach a patient inhaling to produce the gas stream (col. 3, lines 53-61). Therefore it would have been obvious to one of ordinary skill in the art to modify

Art Unit: 3761

the method of Smith/Ohki to include the step of Newell et al. to eliminate the need to replace a pressurized gas source when it is exhausted.

33. As to claim 29, Smith/Ohki/Newell teaches a method as in claim 28, further comprising a mouthpiece 331 coupled to the housing that is adapted to receive a patient's mouth to permit the patient to produce a gas stream that is flowed through the hole in the bottom end of the receptacle and into extraction tube to draw the powder from the cavity and into the extraction tube where the powder is entrained in the gas stream to form an aerosol (col. 3, lines 54-61).

34. Claims 7, 13, 14-20, 22, 30-34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Ohki et al. in further view of Melton, Jr. et al. 3,967,761.

35. As to claim 7, Smith/Ohki teaches the method of claim 6. It should be noted that Smith/Ohki fails to teach wherein the bottom end of the receptacle includes a raised central region that extends upwardly into the cavity, and further comprising aligning the extraction tube with the raised central region such that the bottom end of the extraction tube is spaced apart from the raised central region. However, Melton, Jr. et al. teaches wherein the bottom end of the receptacle includes a raised central region that extends upwardly into the cavity (fig. 11 and 12), and further comprising aligning the extraction tube with the raised central region such that the bottom end of the extraction tube is spaced apart from the raised central region (fig. 13). Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Smith/Ohki to include

the method step of aligning the extraction tube with the raised central region of Melton, Jr. et al. to ensure proper discharge of the medicament.

36. As to claim 13, Smith/Ohki/ Melton, Jr. teaches a method for aerosolizing a powdered medicament, the method comprising: providing a receptacle comprising a receptacle body 342 that defines an enclosed cavity, wherein the receptacle body has a top end and a bottom end, and wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity (fig. 11 and 12); inserting a bottom end of an extraction tube 370 into the cavity such that the bottom end of the extraction tube is aligned with the raised central region and is spaced above the bottom end of the receptacle; forming vents in the top end of the receptacle about a periphery of the cavity (col. 17, lines 16-37); and flowing a gas stream through at least a portion of the extraction tube to draw air through the vents and then through the cavity to move the powder in the cavity into the extraction tube where the powder is entrained in the gas stream to form an aerosol (col. 17, lines 49-63).

37. As to claim 14, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13, wherein the receptacle includes a curved wall, and wherein the air flows along the wall to remove substantially all powder from the receptacle (fig. 12 c).

38. As to claim 15, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13, wherein the air drawn by the gas stream flows through a flow area, and further comprising reducing the flow area as the air flows through the receptacle and the extraction tube to accelerate the flow of air through the receptacle (fig. 19).

39. As to claim 16, Smith/Ohki/Ballini teaches a method claim as in claim 15, wherein the vents form a first flow area, wherein a gap between the extraction tube and the bottom end of the receptacle defines a second flow area, and wherein a cross section of the extraction tube defines a third flow area, and wherein the first flow area is greater than the second flow area, and wherein the second flow area is greater than the third flow area (fig. 19).

40. As to claim 17, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 15. It should be noted that Smith/Ohki/ Melton, Jr. fails to teach wherein the ration of the first flow area to the second flow are and the to the third flow area is about 2.0:1.5:1.0. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to design the flow areas as recited in the claim because the particulars of the flow areas are a mere design choice obtained through routine observation and experimentation. Furthermore, the applicant has not disclosed why the particulars of the dimension are of importance or solves a stated problem or provides an advantage over the prior art.

41. As to claim 18, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13, further comprising piercing a hole through the top end of the receptacle and inserting the extraction tube into the cavity through the hole in the top end (col. 17, lines 16-37).

42. As to claim 19, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13, further comprising introducing the gas stream into the extraction tube at a location spaced apart from the bottom end of the extraction tube (col. 8, lines 9-16).

Art Unit: 3761

43. As to claim 20, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13, further comprising forming a hole in the bottom end of the receptacle body, and flowing the gas stream through the hole in the bottom end (col. 8, lines 9-16).

44. As to claim 22, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13, further comprising releasing an amount of pressurized gas to produce the gas stream (col. 13, lines 22-26).

45. As to claim 30, Smith/Ohki/Melton, Jr. teaches the apparatus as in claim 28 further comprising a flow insert to control spacing of the extraction tube relative to the receptacle (col. 23, lines 32-46).

46. As to claim 31, Smith/Ohki/ Melton, Jr. teaches a system for aerosolizing a powdered medicament, the system comprising: at least one receptacle 342 that comprises a receptacle body that defines an enclosed cavity, and wherein the bottom end of the receptacle body includes a raised central region that extends upwardly into the cavity wherein the receptacle body has a top end and a bottom end (fig. 11 and 12); and an aerosolizing apparatus having a holder for holding the receptacle 304, an extraction tube 370 that is insertable into the cavity, a vent forming device 372 to form multiple vents in the top end of the receptacle about a periphery of the cavity (fig. 19).

47. As to claim 32, Smith/Ohki/ Melton, Jr. teaches a system as in claim 31, further comprising a pressure source for producing a high pressure gas stream within at least a portion of the extraction tube to draw air through the vent to move the powder from the cavity and into the extraction tube where the powder is entrained in the high pressure gas stream to form an aerosol (col. 17, lines 49-63).

48. As to claim 33, Smith/Ohki/ Melton, Jr. teaches the apparatus as in claim 32, further comprising a flow insert to control spacing of the extraction tube relative to the receptacle (col. 23, lines 32-46).

49. As to claim 34, Smith/Ohki/ Melton, Jr. teaches a system as in claim 32, wherein the receptacle is flat in geometry (fig. 18).

50. As to claim 36, Smith/Ohki/ Melton, Jr. teaches a system as in claim 35, further comprising a pressure source for producing a high pressure gas stream within at least a portion of the extraction tube to draw air through the vents to move the powder from the cavity and into the extraction tube where the powder is entrained in the high pressure gas stream to form an aerosol (col. 17, lines 49-63).

51. As to claim 37, Smith/ Ohki/ Melton, Jr. teaches a system as in claim 36, wherein the receptacle includes a curved wall, and wherein the bottom end of the receptacle includes a raised central region that extends upwardly into the cavity (fig. 11 and 12).

52. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Ohki et al. in further view of Melton, Jr. et al. in further view of Newell et al.

53. As to claim 21, Smith/Ohki/ Melton, Jr. teaches a method claim as in claim 13. It should be noted the Smith/Ohki/Melton, Jr. fails to teach a patient inhaling to produce the gas stream. However Newell et al. does teach a patient inhaling to produce the gas stream (col. 3, lines 53-61). Therefore it would have been obvious to one of ordinary skill in the art to modify the method of Smith/Ohki/Melton to include the step of Newell et al. to eliminate the need to replace a pressurized gas source when it is exhausted.

Contacts


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Aaron Lewis can be reached on (703) 308-0716. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



MM
July 17, 2002



DENNIS RUHL
PRIMARY EXAMINER